Complete Summary

GUIDELINE TITLE

Diagnosis and management of dental caries throughout life.

BIBLIOGRAPHIC SOURCE(S)

Diagnosis and management of dental caries throughout life. Bethesda MD: Office of Medical Applications of Research (OMAR); 2001 Mar 28. 24 p. [1592 references]

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Dental caries

GUIDELINE CATEGORY

Diagnosis Management Prevention

CLINICAL SPECIALTY

Dentistry
Family Practice
Infectious Diseases
Internal Medicine
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses Dentists Nurses Physician Assistants Physicians Public Health Departments

GUIDELINE OBJECTIVE(S)

To optimize the identification of improved caries diagnostic, prevention, and treatment strategies, and to assess the quality of the data on existing diagnostic and treatment paradigms

TARGET POPULATION

Children and adults at risk for and with dental caries

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. Visual and visual tactile inspection
- 2. Radiography
- 3. Fiberoptic transillumination
- 4. Electrical conductance
- 5. Laser florescence
- 6. Assessment of risks factors

Management/Prevention

- 1. Fluoride varnishes, rinses, and gels (e.g., acidulated phosphate fluoride gel)
- 2. Chlorhexidine varnishes, rinses, and gels
- 3. Products containing noncariogenic sweeteners, such as sorbitol and xylitol
- 4. Combined chlorhexidine, fluoride, and/or sealant applications
- 5. Sealants
- 6. Antimicrobials
- 7. Salivary enhancers
- 8. Behavioral modification
- 9. Other approaches

MAJOR OUTCOMES CONSIDERED

Diagnosis

• Reliability, reproducibility, and validity of diagnostic modalities

Treatment/Prevention

- Dental caries risk
- Dental caries rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The Evidence-based Practice Center (EPC) review and investigative team conducted two detailed searches of the relevant English language literature from 1966 to October 1999 using MEDLINE, EMBASE, and the Cochrane controlled trials register. They did not pursue reports in the gray literature (i.e., information not reported in the periodic scientific literature). The team hand-searched current journals up to the end of 1999.

One search focused on the following diagnostic methods:

- Visual as well as visual tactile inspection
- Radiography
- Fiberoptic transillumination
- Electrical conductance
- Laser fluorescence
- Combinations of these methods, using keywords for the disease (dental caries, tooth demineralization), diagnostic concepts (oral diagnosis, oral pathology, dental radiography), and study characteristics and design

A second search focused on dental caries preventive or management methods, using key words for methods (fluorides, pit and fissure sealants, health education, dental prophylaxis, oral hygiene, dental plaque, chlorhexidine dental sealants, cariostatic agents) and study characteristics and design in addition to the disease key words.

In addition, two days of public meetings were held at which time experts and researchers present their recent findings. Public comment and discussion are also invited.

Further information regarding the search strategies used can be found at the <u>University of Michigan Dentistry Library Web site</u>.

NUMBER OF SOURCE DOCUMENTS

66

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The Evidence-based Practice Center team used in its approach to evaluating the evidence the following rating scheme.

Diagnosis

For the diagnostic question, the strength of evidence was judged in terms of the extent to which it offered a clear, unambiguous assessment of the validity of a particular method for identifying a specific type of lesion on a specific type of surface. The three possible ratings were:

- Good (A). The number of studies is large, the quality of the studies is generally high, and the results of the studies represent narrow ranges of observed sensitivity and specificity.
- Fair (B). There are at least three studies, the quality of the studies is at least average, and the results represent moderate ranges of observed sensitivity and specificity.
- Poor (C). There are less than three studies, or the quality of the available studies is generally lower than average, and/or the results represent wide ranges of observed sensitivities and/or specificities.

Management

For the management studies, the team used a scheme based on several considerations, including the magnitude of the results reported, the quality rating scores of the studies, the number of studies, and the consistency of the results across studies. The Evidence-Based Practice Center team's scientific and clinical directors independently rated the interventions and developed an adjudicated final rating. The four possible ratings were:

- Good (A). Data are sufficient for evaluating efficacy. The sample size is substantial, the data are consistent, and the findings indicate that the intervention is clearly superior to the placebo/usual care alternative.
- Fair (B). Data are sufficient for evaluating efficacy. The sample size is substantial, but the data show some inconsistencies in outcomes between intervention and placebo/usual care groups such that efficacy is not clearly established.
- Poor (C). Data are sufficient for evaluating efficacy. The sample size is sufficient, but the data show that the intervention is no more efficacious than placebo or usual care.
- Incomplete Evidence (I). Data are insufficient for assessing the efficacy of the intervention, based on limited sample size and/or poor methodology.

METHODS USED TO ANALYZE THE EVI DENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Evidence-based Practice Center methodology. Separate quality rating forms were completed by the Evidence-Based Practice Center team's scientific director for the two types of studies. The quality rating scales assessed several elements of internal validity, including study design, duration, sample size, blinding, baseline assessments of differences among groups, loss to follow-up, and examiner reliability. Two items also required each reviewer's subjective assessment of both the internal and external validity of the study.

They compiled the abstracted data in a series of six evidence tables, one each for in vivo and in vitro radiographic studies, studies of management of noncavitated carious lesions and individuals at elevated risk for carious lesions, and studies of special populations of orthodontic patients and patients who received head and neck radiotherapy. The team then graded the evidence summarized in the tables.

Consensus Panel methodology. The Panel reviewed all available evidence, including but not limited to the Evidence Reports, experts comments, and public input.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Answering predefined questions, the National Institutes of Health (NIH) Consensus Development Panel on Diagnosis and Management of Dental Caries drafted a statement based on the scientific evidence presented in open forum and the scientific literature. The draft statement was read in its entirety on the final day of the conference and circulated to the experts and the audience for comment. The panel then met in executive session to consider these comments and released a revised statement at the end of the conference.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The statement was made available on the World Wide Web at http://consensus.nih.gov immediately after the conference.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Conclusions

This Consensus Development Conference, the first sponsored by the National Institutes of Health (NIH) on dental caries, provided an excellent venue to describe the great success that has been achieved in reducing caries prevalence. More importantly, it provided a public forum to review both the strengths and weaknesses of current dental caries research and clinical procedures. Effective preventive practices, such as the use of fluoride, sugarless products, and dental sealants were reconfirmed, and clinical studies to identify more conservative but more effective nonsurgical and surgical approaches are to be applauded. However, it was evident that current diagnostic practices are inadequate to achieve the next level of caries management in which noncavitated lesions are identified early so that they can be managed by nonsurgical methods. Some new and sensitive diagnostic approaches were presented to the panel, but concern was raised about the use of histological confirmation of caries presence as an appropriate gold standard. The resolution of these issues requires that surrogate markers, validated by histological confirmation, be developed. Once these surrogate markers of dental caries activity are validated, rapid advances in our understanding of the caries process are certain to follow.

In spite of optimism about the future, the panel was disappointed in the overall quality of the clinical data set that it reviewed. Far too many studies used weak research designs or were small or poorly described, and consequently had questionable validity. There was a clear impression that clinical caries research is underfunded, if not undervalued. Moreover, incomplete information on the natural history of dental caries, the inability to accurately identify early lesions and/or lesions that are actively progressing, and the absence of objective diagnostic methods are troubling. Several systematic reviews of the literature presented at the Consensus Development Conference concluded that the majority of the studies were inadequate, and it is clear that a major investment of research and training funds is required to seize the current opportunities.

This is not to say that the diagnostic, preventive, and treatment techniques currently used do not work, but rather that earlier studies to support their efficacy do not meet current scientific standards. Indeed, given the dramatic improvements in reducing dental caries prevalence in the past 30 years, both consumers and health professionals should not depart from the practices which are likely to have contributed to this oral health improvement, including the use of a variety of fluoride products, dietary modification, pit and fissure sealant, improved oral hygiene, and regular professional care. In addition, pending new data, clinicians should apply both preventive and therapeutic interventions in the manner in which they have been studied. When solid confirmation of the effectiveness of promising new diagnostic techniques, nonsurgical treatments of noncavitated lesions, and conservative surgical interventions for cavitated lesions are obtained, dental health professionals and the public should embrace them rapidly in anticipation of attaining still higher levels of oral health. None of these anticipated advances will be achieved, however, in the absence of a progressive, third-party payment system that acknowledges its responsibility to compensate

providers adequately to ensure that the next generation of conservative therapy can be enjoyed by the American people.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by an Evidence-based Practice Center review, expert comments, and public input.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Diagnosis

Increased detection of dental caries

Treatment/Prevention

- Improved identification of dental caries risk
- Decreased dental caries rates

Prevention

- Acidulated phosphate fluoride gel (APF). Evidence for the efficacy of APF gel applied 1-2 times per year was consistently positive.
- Fluoride varnish. The evidence for the benefit of applying fluoride varnish to permanent teeth is generally positive. In contrast, the evidence for effectiveness of fluoride varnish applied to primary teeth is incomplete and inconsistent.
- Chlorhexidine gels. The evidence for the use of chlorhexidine gel is moderately strong, although many of the studies demonstrating its effectiveness used concomitant preventive measures.
- Pit and fissure sealants. Pit and fissure sealants have been demonstrated to be effective in the primary prevention of caries, and their effectiveness remains strong as long as the sealants are maintained.
- Products containing noncariogenic sweeteners. The evidence for both sorbitol and xylitol is positive, although the evidence for xylitol is stronger.
- Combination interventions. There is reason to believe that preventive strategies may be more effective when they are combined than when they are administered individually. Numerous combination interventions have been studied. In general, these combination treatments have been shown to be effective in preventing caries in children.

Treatment

- Fluoride. The research data on fluorides in water and dentifrices support their efficacy. The data also support the use of fluoride varnishes. For rinses and gel applications the evidence is promising but not definitive.
- Chlorhexidine. For varnishes and gels, the data are promising. Research data showing effectiveness of chlorhexidine rinses are lacking.
- Sealants. The use of pit and fissure sealants is supported by the data.
- Combinations. Combinations of chlorhexidine, fluoride, and/or sealants are suggestive of efficacy.
- Antimicrobials. Although mutans streptococci is recognized as part of the
 pathology of caries and therefore an antimicrobial approach would seem
 reasonable, current data are inadequate to support antimicrobial treatments
 other than chlorhexidine and fluorides, both of which have antibacterial
 properties.
- Salivary Enhancers. Although there are indications that pathologically low salivary flow, as a consequence of Sjogren's syndrome or as an effect of head/neck radiation treatment or xerostomic medications, is associated with caries, there is no evidence that low normal salivary flow produces a similar outcome.
- Behavioral Modification. Most interventions require patient adherence, and current data provide some support for the efficacy of office-based behavioral interventions.

Subgroups Most Likely to Benefit:

Certain high-risk populations may benefit more than other populations from prevention interventions.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This statement is an independent report of the panel and is not a policy statement of the National Institutes of Health (NIH) or the Federal Government.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Diagnosis and management of dental caries throughout life. Bethesda MD: Office of Medical Applications of Research (OMAR); 2001 Mar 28. 24 p. [1592 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2001 Mar

GUIDELINE DEVELOPER(S)

National Institute on Dental and Craniofacial Research - Federal Government Agency [U.S.]

National Institutes of Health Consensus Development Panel on Diagnosis and Management of Dental Caries - Independent Expert Panel

GUI DELI NE DEVELOPER COMMENT

NIH Consensus Statements are prepared by a nonadvocate, non-Federal panel of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session; (2) questions and statements from conference attendees during open discussion periods that are part of the public session; and (3) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the consensus panel and is not a policy statement of the NIH or the Federal Government.

The primary sponsors of this conference were the National Institute of Dental and Craniofacial Research and the NIH Office of Medical Applications of Research. The conference was cosponsored by the National Institute on Aging and the U.S. Food and Drug Administration.

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

The National Institutes of Health (NIH) Consensus Development Panel on Diagnosis and Management of Dental Caries

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Consensus Development Panel Members: Michael C. Alfano, DMD, PhD; Ian D. Coulter, PhD; Meghan B. Gerety, MD; Thomas C. Hart, DDS, PhD; Peter B. Imrey, PhD; Linda LeResche, ScD; Joseph Levy, MD; Russell V. Luepker, MD, MS; Alan G. Lurie, DDS, PhD; Roy C. Page, DDS, PhD; Leslie A. Rye, DDS, MST; Lucille Smith; Clay B. Walker, PhD.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All of the panelists who participated in the National Institutes of Health (NIH) conference and contributed to the writing of this consensus statement were identified as having no financial or scientific conflict of interest, and all signed conflict of interest forms attesting to this fact.

ENDORSER(S)

Food and Drug Administration (U.S.) - Federal Government Agency [U.S.] National Institute on Aging - Federal Government Agency [U.S.]

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDFLINF AVAILABILITY

Electronic copies: Available from the <u>NIH Consensus Development Conference Program Web site</u>. Also available from the <u>National Library of Medicine Health Services/Technology Assessment Text (HSTAT) Web site</u>.

Print copies: Available from the NIH Consensus Development Program Information Center, PO Box 2577, Kensington, MD 20891; Toll free phone (in U.S.), 1-888-NIH-CONSENSUS. email: consensus statements@mail.nih.gov.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- A complete bibliography prepared by the National Library of Medicine (NLM) is available at the <u>NLM Web site</u>.
- Diagnosis and management of dental caries. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ), 2001 Feb. (Evidence

report/technology assessment: no. 36). AHRQ Publication No. 01-E055. Available from the AHRQ Web site: <u>Summary</u>; <u>File Download</u>.

- Program and Abstract Book available in <u>Portable Document Format (PDF)</u>.
- A search summary is available from the <u>University of Michigan Dentistry Library Web site</u>.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on September 17, 2001. The information was verified by the guideline developer as of October 25, 2001.

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